

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 5622

Serial No.: 09/654,227

Examiner: M. Bandy

Filed: August 31, 2000

Group Art Unit: 1617

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

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**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

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- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
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  - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
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is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

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☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

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- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
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**CITED MATERIALS**

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Copies of the materials listed are attached (except for the foregoing).

**NON-ENGLISH LANGUAGE REFERENCES**

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
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- X = document of particular relevance when it is taken alone  
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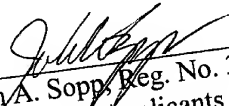
**OTHER INFORMATION**

None

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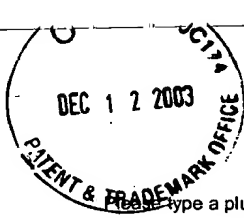
Respectfully submitted,

  
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Attorney Docket No.: PLOVIN-1A

Date: December 10, 2003



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Sheet 1 of 4

### Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,824,667		Spona et al.	10-20-1998
	A4	6,083,528		Elliesen et al.	07-04-2000
	A5	6,121,465		Mohr et al.	09-19-2000
	A6	RE37,564		Spona et al.	02-26-2002

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	DE	3022337	A1	Eiger et al.	01-07-1982		
	B2	WO	95/07081	A1	Koninckx	03-16-1995		
	B3	WO	97/10827	A1	Petit et al.	03-27-1997		
	B4	WO	98/27929	A2	Nashed	07-02-1998		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71	
	C3	Oelkers et al., (1991) "Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the Renin-Aldosterone System in Normal Women" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 73, No. 4, 837-842	
	C4	Oelkers, "Effects of oral contraceptives on the renin - aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206	
	C5	Kincl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84	

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Attorney Docket Number	PLOVIN-1A

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	C6	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827	
	C7	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626	
	C8	Chakmakjian et al., "Bioavailability of Progesterone with Different Modes of Administration," <i>The Journal of Reproductive Medicine</i> , Vol. 32, No. 6, June 1987, pp. 443-448	
	C9	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951	
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	C15	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C16	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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First Named Inventor Wolfgang HENKEL et al.

Group Art Unit 1617

Examiner Name M. Bahar

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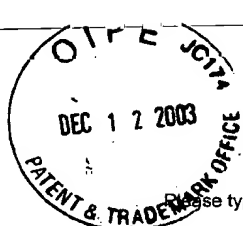
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	C24	Wilson et al., (1984) "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C25	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
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	C28	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 $\beta$ Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
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	C30	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
	C31	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p.987-993	
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	C34	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
	C35	Oelkers, "Reply to Letter to the Editor," <i>Gynecol Endocrinol</i> , 2000, 14:476-478	

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NON PATENT LITERATURE DOCUMENTS		
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	C36	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194
	C37	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
	C38	"Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," <i>JAMA</i> , January 18, 1995, Vol. 273, No. 3, 199-208
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	C45	Pitt et al., "The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure," <i>The New England Journal of Medicine</i> , Vol. 341, No. 10, September 2, 1999, 709-717
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